

MULTI-SYMPTOM ALLERGY- acetaminophen, chlorpheniramine maleate, phenylephrine hcl tablet

Walgreen Company

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Walgreens 44-559

Active ingredients (in each gelcap)

Acetaminophen 325 mg

Chlorpheniramine maleate 2 mg

Phenylephrine HCl 5 mg

Purpose

Pain reliever

Antihistamine

Nasal decongestant

Uses

- temporarily relieves these symptoms of hay fever or other upper respiratory allergies:
 - sinus congestion and pressure
 - nasal congestion
 - runny nose and sneezing
 - headache
 - minor aches and pains
- temporarily relieves these additional symptoms of hay fever:
 - itching of the nose or throat
 - itchy, watery eyes
- helps clear nasal passages
- helps decongest sinus openings and passages

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take

- more than 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

If a skin reaction occurs, stop use and seek medical help right away

Do not use

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.
- if you have ever had an allergic reaction to this product or any of its ingredients

Ask a doctor before use if you have

- liver disease
- diabetes
- heart disease
- high blood pressure
- thyroid disease
- difficulty in urination due to enlargement of the prostate gland
- a breathing problem such as emphysema or chronic bronchitis
- glaucoma

Ask a doctor or pharmacist before use if you are

- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers

When using this product

- **do not exceed recommended dosage**
- excitability may occur, especially in children
- alcohol, sedatives, and tranquilizers may increase drowsiness
- drowsiness may occur
- use caution when driving a motor vehicle or operating machinery
- avoid alcoholic beverages

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur
- pain or nasal congestion gets worse or lasts more than 7 days
- new symptoms occur
- fever gets worse or lasts more than 3 days
- redness or swelling is present

These could be signs of a serious condition.

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

In case of accidental overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

- **do not take more than directed**
- adults and children 12 years and over
 - take 2 gelcaps every 4 hours
 - do not take more than 10 gelcaps in 24 hours
- children under 12 years: ask a doctor

Other information

- contains FD&C Yellow #5 (tartrazine) as a color additive
- **TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN**
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- see end flap for expiration date and lot number
- avoid high humidity

Inactive ingredients

cornstarch, croscarmellose sodium, crospovidone, FD&C red #3, FD&C red #40, FD&C yellow #5, FD&C yellow #6, gelatin, hydroxypropyl cellulose, hypromellose, iron oxide black, iron oxide red, iron oxide yellow, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, propylene glycol, shellac glaze, silicon dioxide, stearic acid, titanium dioxide

Questions or comments?

1-800-426-9391

Principal display panel

NDC 0363-0559-08

Walgreens

MULTI-SYMPTOM

Allergy

ACETAMINOPHEN 325 mg / PAIN RELIEVER
CHLORPHENIRAMINE MALEATE 2 mg / ANTIHISTAMINE
PHENYLEPHRINE HCl 5 mg / NASAL DECONGESTANT

GELCAPS

- Relief of runny nose, sneezing, itchy, watery eyes & itchy throat or nose

24 GELCAPS

FAST-RELEASE QUICK GELS™

Actual Size

TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING

Walgreens Pharmacist Recommended
Walgreens Pharmacist Survey

50844 ORG071855908

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MULTI-SYMPTOM Allergy

ACETAMINOPHEN 325 mg / PAIN RELIEVER
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Walgreens

Drug Facts COMPLETE PRODUCT INFORMATION

Active ingredients (in each gelcap)
 Acetaminophen 325 mg Pain reliever
 Chlorpheniramine maleate 2 mg Antihistamine
 Phenylephrine HCl 5 mg Nasal decongestant

Uses ■ temporarily relieves these symptoms of hay fever or other upper respiratory allergies:
 ■ runny nose and sneezing
 ■ nasal congestion ■ minor aches and pains
 ■ headache ■ sinus congestion and pressure

Drug Facts (continued)

prostate gland ■ glaucoma ■ thyroid disease
 Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin
 ■ taking sedatives or tranquilizers
 When using this product
 ■ do not exceed recommended dosage
 ■ excitability may occur, especially in children
 ■ alcohol, sedatives, and tranquilizers may increase drowsiness ■ drowsiness may occur
 ■ use caution when driving a motor vehicle or operating machinery ■ avoid alcoholic beverages

Stop use and ask a doctor if
 ■ nervousness, dizziness, or sleeplessness occur
 ■ pain or nasal congestion gets worse or lasts more than 7 days ■ new symptoms occur
 ■ fever gets worse or lasts more than 3 days
 ■ redness or swelling is present
 These could be signs of a serious condition.
 If pregnant or breast-feeding, ask a health professional before use.
 Keep out of reach of children. In case of accidental overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions ■ do not take more than directed
 ■ adults and children 12 years and over ■ take 2 gelcaps every 4 hours
 ■ do not take more than 10 gelcaps in 24 hours
 ■ children under 12 years: ask a doctor

Other information
 ■ contains FD&C Yellow #5 (tartrazine) as a color additive

Drug Facts (continued)
Inactive ingredients corn starch, croscarmellose sodium, crospovidone, FD&C red #3, FD&C red #40, FD&C yellow #5, FD&C yellow #6, gelatin, hydroxypropylcellulose, hypromellose, iron oxide black, iron oxide red, iron oxide yellow.

Drug Facts (continued)
 ■ temporarily relieves these additional symptoms of hay fever: ■ itchy, watery eyes
 ■ itching of the nose or throat
 ■ helps clear nasal passages
 ■ helps decongest sinus openings and passages

Warnings
 Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take more than 4,000 mg of acetaminophen in 24 hours ■ with other drugs containing acetaminophen ■ 3 or more alcoholic drinks every day while using this product
 Allergic alert: Acetaminophen may cause severe skin reactions. Symptoms may include:
 ■ skin redness ■ blisters ■ rash
 If a skin reaction occurs, stop use and seek medical help right away.

Do not use ■ with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
 ■ if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.
 ■ if you have ever had an allergic reaction to this product or any of its ingredients

Ask a doctor before use if you have
 ■ a breathing problem such as emphysema or chronic bronchitis ■ high blood pressure ■ heart disease ■ diabetes ■ liver disease ■ difficulty in urination due to enlargement of the prostate gland

Drug Facts (continued)
 ■ avoid high humidity
 ■ see end flap for expiration date and lot number

Drug Facts (continued)
TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN ■ store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
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Walgreens Pharmacist Recommended
 Walgreens Pharmacist Survey

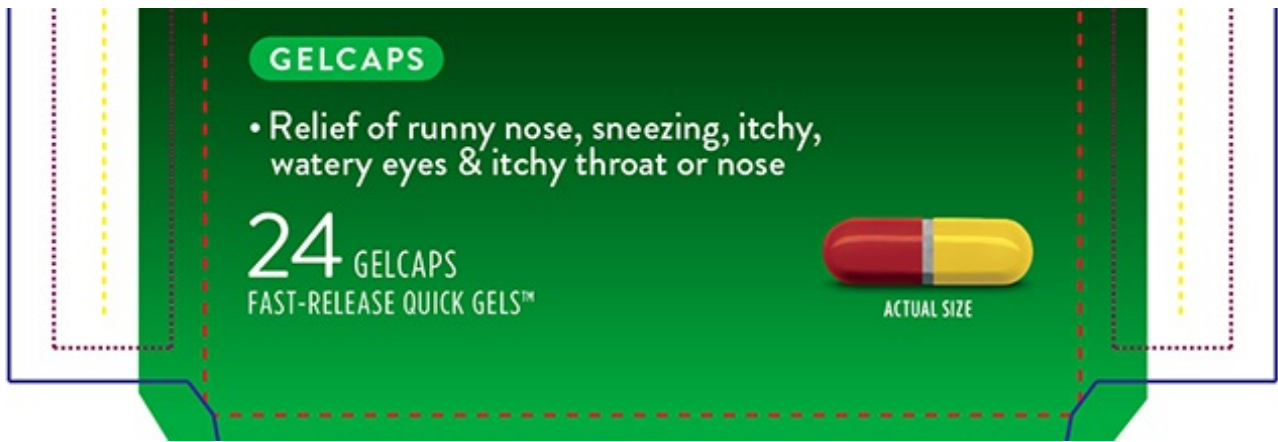
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ORG0818-F
 REV1018

Drug Facts (continued)
 magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, propylene glycol, stearic acid, silicon dioxide, stearic acid, titanium dioxide

TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING
 Lot/Exp area at minimum size
 1.25 x .5"

Questions or comments? 1-800-426-9391



44-559

MULTI-SYMPATOM ALLERGY

acetaminophen, chlorpheniramine maleate, phenylephrine hcl tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0363-0559
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
CHLORPHENIRAMINE MALEATE (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)	CHLORPHENIRAMINE MALEATE	2 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients

Ingredient Name	Strength
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
GELATIN (UNII: 2G86QN327L)	
FD&C RED NO. 3 (UNII: PN2ZH5LOQY)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POVIDONE (UNII: FZ989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSPVIDONE (UNII: 2S7830E561)	

HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
STARCH, CORN (UNII: O8232NY3SJ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	

Product Characteristics

Color	YELLOW, RED	Score	no score
Shape	OVAL	Size	19mm
Flavor		Imprint Code	L;9
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-0559-08	2 in 1 CARTON	03/27/2008	
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:0363-0559-22	4 in 1 CARTON	03/27/2008	10/08/2016
2		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	03/27/2008	

Labeler - Walgreen Company (008965063)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	MANUFACTURE(0363-0559)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	PACK(0363-0559)